Service Manual

Combilyzer VA

Semi Automated Strip Reader

Cat.-No.: 16600/2

CE

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The operation of the COMBILYZER VA is introduced in its User's Manual. If the user follows the instructions and watches the precautions described in that manual, the equipment will support the laboratory activities long lasting and free of errors.

However, even professionally operated electronic equipment can fail to work despite their proper maintenance. This manual will guide you how to troubleshoot the possible COMBILYZER VA failures and malfunction, also advising "what to do" when those operational problems arise.

Please, also note that only a limited number of failures can be repaired among the conditions of the medical laboratories. In most cases the equipment need to be sent back to the distributor (who might forward it to the manufacturer) in order to have it thoroughly adjusted or repaired.

The manufacturer built into the control program (firmware) of the equipment some modules specifically supporting the troubleshooting functions. With the help of these functions a trained expert can decide whether to maintain the equipment locally or send it back to the manufacturer asking professional help. The trained user can enter the operational mode – named CHECK mode – that offers the troubleshooting functions by turning on the equipment while keeping pressed for about 5 seconds the right upper control key on the key-pad. Releasing the control key the equipment will be controlled by the CHECK mode program.

Troubleshooting in CHECK mode

1 THE CORRECT MEASURING FUNCTIONALITY TEST OF THE OPTICAL SYSTEM

1.1 Tools Applied During the Test:

a. Grey Stripped Calibration Sheet made of plastic (Figure 1.)
Sheet with 3 strips: strip width 20 mm, the strip leading edge distance from the front edge of the sheet: 30 mm

Colour	Munsell ref. No.
White	N9
Black	N2
Grey	N5

b. Sheet with 7 colour-strips, made of plastic: colour strip width 12 mm, first colour strip leading edge distance from the front edge of the sheet: 20 mm

Red	5R 7/10 matte	(21066)
Yellow	5Y 8-12 matte	(21335)
Yellow-green	5GY 8/10 matte	(21525)
Green	5G 7/10 matte	(21689)
Green-blue	5BG 7/8 matte	(21800)
Blue	5B 7/8 matte	(21905)
Purple	5P 7/8 matte	(22169)

Sheets shall be checked visually before controls. Sheets must be straight, surfaces free of contamination and physical damaged/scratches.

1.2 Test Method for Checking of the Measurement Accuracy

The seven colours plus white specified on the control sheet are to be tested in Check – AB mode performing at least five measurements subsequently. (Measurements repeated 5 times, while no touching/moving the sheet). The averages of the measurement values need to be calculated, the minimum and the maximum values are also considered for each pad position. In the case of properly operating optical system, the difference of the minimum and maximum values from the average of the specific pad will not exceed +/- 1 in AB.

1.3 Test Method for Checking of the Meter to Meter Deviation

The seven colours plus white specified in the control sheet are to be tested in Check – AB mode performing at least five measurements subsequently with the instruments to be checked. The averages of the measurement values need to be calculated for each pad. The average deviation of two devices for each pad will not exceed 2 in AB. (The deviation from the overall average of three factory reference readers will not exceed +/- 1 in AB.)

2. THE STEPS OF THE TROUBLE-SHOOTING:

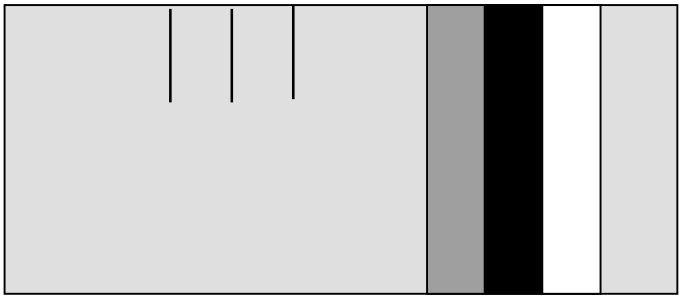


Figure 1. The grey-stripped Service Sheet

Remove the test-strip bumper and place the Service Sheet (Figure 2) on the conveyor, aligning its side to the edge of the conveyor (see: figure 2)

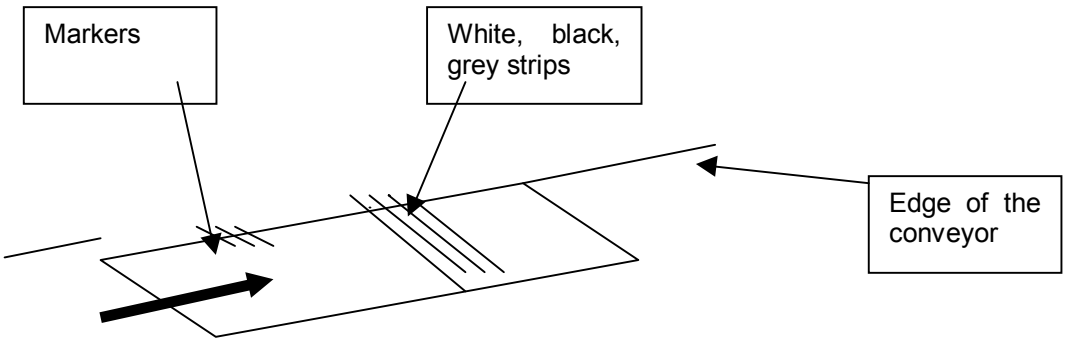


Figure 2. Alignment of the Service Sheet after removing the strip bumper

The first reference field to be checked is the white one, (then black and grey) must be positioned exactly under the optical detector inside the reading head. There are marker lines on the sheet to help to adjust the correct position: the marker must be in line with the cabinet's edge, as it is shown in the Figure 3.

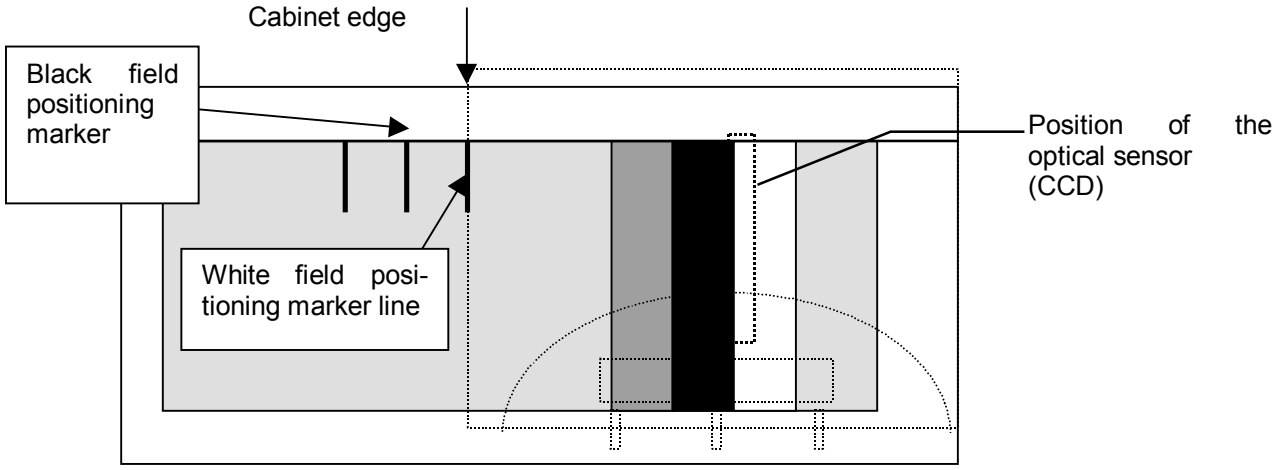


Figure 3. The correctly positioned Service Sheet

2.2 Check Mode

Now, in order to perform the optical system test, you need to enter the Check Mode (as described above: turning on the equipment while keeping pressed down the right upper control button for about 5 sec). You can navigate in the menu-system by activating the control button right below the selected option.

The control parameter values below need to be pre-set while proceeding in the menu system:

Clear User White ?
'User White' parameter is not applied presently for any purpose. Always select: No

2.2.1 Output (where to send the result data)

PRN Printer selected
RS485 the barcode/keyboard interface RS485 (five pin) used. Image data are sent to the connected host.

2.2.2 Result Data Format

Normal the results (measurement values) will be printed out (in the pre-programmed, selectable measurement units).
RGB the results will be printed out in analogue (red, green, and blue) values in the RGB colour system
AB the results are printed out in analogue (red, green, and blue) values in the AB colour system

2.2.3 Trigger

(this option will be enabled only if the RGB or AB result data format [see above] was selected)
Normal invokes a normal measurement cycle: the conveyor belt forwards the test strip under the sensor head, then a normal reading follows.
Button The conveyor belt stays halted. The sensor head executes a reading Operation answering every right button press. This mode serves only test function: evaluating the RGB or AB values.

2.2.4 Calibration Data

Display the calibration data display mode selection
Normal the detected (R,G,B components) light wave values of the illuminated Calibration sheets (either Grey striped and 7 colour striped) will be printed out for each pad position together with the data how the program evaluated the measured data
Send Debug option to get the calibration data by pixels. No need for the user using of this option

The information block (structure is shown below) is sent via RS 232 serial line selecting this mode. The serial line control setting is 9600, 8, N, 1.

The structure of the sent binary file:

Grey strip RED component values	- 720 bytes, (for each pixel of the CCD)
White strip RED component values	- 720 bytes, (for each pixel of the CCD)
Grey strip GREEN component values	- 720 bytes, (for each pixel of the CCD)
White strip GREEN component values	- 720 bytes, (for each pixel of the CCD)
Grey strip BLUE component values	- 720 bytes, (for each pixel of the CCD)
White strip BLUE component values	- 720 bytes, (for each pixel of the CCD)
checksum	- 3 words

Select the following settings if you need to perform a test measurement after entering in CHECK mode and want to get the RGB component values of results in printed out form:

Output		PRN
Result	data format	RGB
Trigger		BUTTON
Calibr. data		NORMAL

Important:
*In general, perform all the test procedure in about **5 minutes** after switching on the equipment. (warming up period need to be considered)*

2.3 Measurement Cycle

The illumination switches on, but the conveyor belt keeps standing. The instrument executes a measurement cycle answering an activation of the right control button and the results will be printed out in RGB format.
* Please note, that the measurement cycle need some time while loading the image into memory of the COMBILYZER VA, so wait for about 2 sec before reactivating the button again.

The red, green and blue component values can be read next to the abbreviation of the reagent parameter names. In this test report the parameters names refer only to the position along the strip.

Check all measured values of the three reference fields (white, black, grey) printed out by components (RGB) against the following reference ranges.

WHITE	160	-	180
BLACK	5	-	15
GRAY	30	-	45

If all the measured values are within the given ranges, the optical system (CCD, lens, mirror system), works properly and the calibration of the COMBILYZER VA is good.

Values out of the ranges refer to improper operation of the optical system.
Maintenance (Cleaning) procedure is advisable.

If the values after the re-calibration are within the given ranges, the optics (CCD, lens, mirrors), and the white calibration of the COMBILYZER VA is good.

If the cleaning does not improve the operation, the equipment must be return to the manufacturers' professional service.

The image sharpness can be checked by reading the barcode printed on the Calibration Strip. If the COMBILYZER VA is able to read the barcode safely, the image sharpness should be considered good.

3 RE-CALIBRATION

COMBILYZER VA needs be re-calibrated in cases, when the optical system was replaced or repaired.

The re-calibration process is always done by manufacturer.

4 INTERFACE

4.1 Introduction

The COMBILYZER VA can be connected to a PC or to any Host device on the RS-232 serial line, with the serial RS-232 cable.
There are two modes of communication: unidirectional and bi-directional.
The mode can be chosen under the MENU/SETUP/OUTPUT/SERIAL menu:
PC - unidirectional
NETW. - bi-directional

4.2 Hardware Features

Interface cable:

COMBILYZER VA 9 point CANON FEMALE	
	1
Tx	2
Rx	3
	4
GND	5
	6
	7
	8
	9

Host 9 point CANON MALE	
1	
2	RxD
3	TxD
4	
5	GND
6	
7	
8	
9	

The cable is a 3 core shielded cable, the shield is connected to the GND on the PC side.

The parameters of the communication:

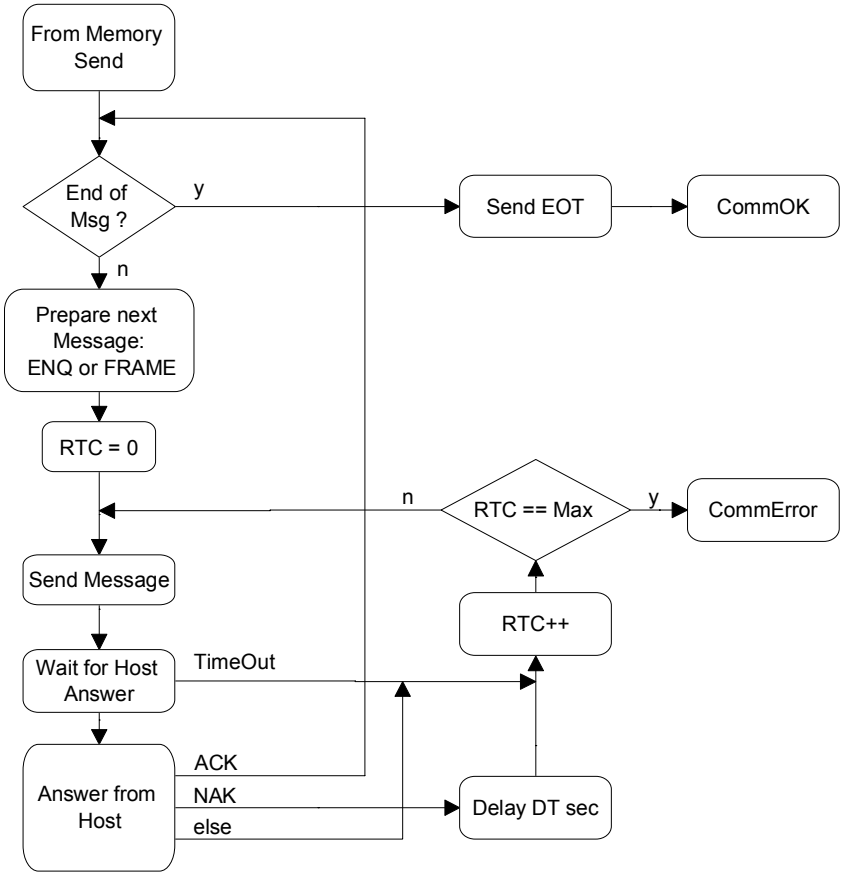
Parameter	**Value**
Baudrate	9600
Databits	8
Stop bits	1
Parity	No

4.3 Unidirectional Mode

This mode is recommended to whom, who simply want to send data to a PC, using a simple terminal program.
The mode can be set by the MENU/SETUP/OUTPUT/SERIAL/PC setting.
The COMBILYZER VA sends out the same character string as which is printed out in this mode.
The sending is in ASCII code, 24 characters/line, in CR format.
The sending is not depends on whether the data flow is received or not.

4.4 Bidirectional Mode

Use this mode to join the COMBILYZER VA to the laboratory network.
In this mode, the stored reports can be sent to the Host, in controlled, bi-directional data flow.
The sending is available by choosing the MEMORY/.../SEND menu.
The communication is initiated by the COMBILYZER VA.
The protocol of the data flow is the following:



Where

COMBILYZER VA	Host	Comment
ENQ		COMBILYZER VA wants to send
FRAME		Report of a measurement
	ACK	Host can receive
	NACK	Host can not receive
	Others	
		Retry count (RTC), max =5
		delay time (DT)=15 sec
		time out =15 sec

The Structure of a FRAME
Everything is in ASCII, except STX and ETX (pl 0 = 30h)

Name	Length (ASCII character)	Comment
STX	1	'Start of text' - Frame start
M	1	Identification mode : 0 - Sequence number 1 - Patient ID
No	3	The sequence number in 3 digits
Pat.ID	15	The Patient ID, if it was given by the barcode reader or by a keyboard, else SPACE
Time	10	Date of the measurement in yyyy/mm/dd format
Strip type	1	The code result conversion can be done based on it
Result	12	Result of the measurement by PADs
ETX	1	end of the information
CHK	2	checksum= XOR for the parts within STX and ETX

The strip-type code is the following:

Code	Type
1	COMBINA 11S

The PADs are identified in the 'Result' string by those order:

position	1	2	3	4	5	6	7	8	9	10	11	12
PAD	BIL	UBG	KET	ASC	GLU	PRO	BLD	PH	NIT	LEU	empty	SG

4.5 Example

The printed result:

URINALYSIS Combina 11S
No: **30**.
Pat ID : Heyer Roland
2003/5/26 10:49

SG	**1.000**		
*LEU	**25**	Leu/µl	**+**
NIT	**neg**		
pH	**7**		
ERY	**neg**		
PRO	**neg**		
GLU	**norm**		
ASC	**neg**		
KET	**neg**		
UBG	**2**	mg/dl	**+**
*BIL	**1**	mg/dl	**+**

.....

The FRAME data flow of this report is the following (assuming Seq. no. identification):
<>- space

Sent character	Length	Comment
STX	1	'Start of text' - Frame start
0	1	Identification code
13	3	The sequence number in 3 digits
Heyer Roland	15	Patient ID
2003/5/26	10	Date of measurement
1	1	Strip type
0100421142◊◊	12	Results of the measurement
ETX	1	End of information
xx	2	checksum= XOR for the parts within STX and ETX

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